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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,768	11/07/2005	Enno Klussmann	Gulde-0058	6937

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1652	

NOTIFICATION DATE	DELIVERY MODE
04/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/526,768	KLUSSMANN ET AL.	
	Examiner	Art Unit	
	SHERIDAN SWOPE	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July & 30 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,22 and 23* is/are pending in the application.

4a) Of the above claim(s) *5-8 and 11-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9,10,22 and 23* is/are rejected.

7)☒ Claim(s) *18 19 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Action of September 1, 2009 withdrew the finality of the Action of March 20, 2009. The non-final Action of September 1, 2009 did not consider the filing of July 20, 2009. The claims of the filings of July 20 and November 30, 2009 are identical. The filings of July 20 and November 30, 2009, including all arguments, are considered herein. It is acknowledged that applicants have added Claims 22 and 23. Claims 1-19, 22, and 23 are pending. Claims 5-8 and 11-17 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1-4, 9, 10, 18, 19, 22, and 23 are hereby considered.

Claims-Objections

Claim 22 is provisionally objected to, under 37 CFR 1.75, as being a substantial duplicate of Claim 1. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 1, 3, 4, 9, and 10 under 35 U.S.C. 112, first paragraph/enablement, for essentially the same reasons explained in the prior actions, is maintained. Claims 22 and 23 are herein rejected under 35 U.S.C. 112, first paragraph/enablement, for the same reasons.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments. These arguments are not found to be persuasive for the reasons set forth in each reply.

(A) Reconsideration of this rejection, in view of the foregoing amendments, further in view of the precedential opinion issued by the United States Board of Patent Appeals and Interferences (Exparte Kubin, Appeal No. 2007-0819, B.A.P.I. 2007) is earnestly solicited.

(A) Reply: It is acknowledged that the claims have been amended. However, Claims 1, 22, and 23 are so broad as to encompass the genus of any nucleic acid molecule comprising a polynucleotide having at least 95% or 90% identity with any nucleic acid molecule comprising SEQ ID NO: 1, wherein said genus of nucleic acid molecules encodes a polypeptide that binds to the PKA regulatory subunit II. Said genus encompasses a sub-genus of nucleic acid molecules, wherein the region not homologous to SEQ ID NO: 1 encodes a polypeptide sequence that binds to PKA regulatory subunit II. The specification fails to provide any example of said sub-genus or to provide guidance as to how to make and use the encompassed nucleic acid molecules. Identification of nucleic acid molecules having the desired structural and functional characteristics requires undue experimentation.

It is unclear which issues discussed by Exparte Kubin are being referred to. Therefore, the Office cannot make any reply.

(B) The genus of the molecules claimed herein is small enough that the skilled artisan can output each and every sequence using routine computational methods.

(B) Reply: By use of "comprising" language, the genus of any nucleic acid molecule comprising a polynucleotide having at least 95% or 90% identity with any nucleic acid molecule

comprising SEQ ID NO: 1, wherein said genus of nucleic acid molecules encodes a polypeptide that binds to the PKA regulatory subunit II, is essentially unlimited.

(C) Moreover, insofar as the structural determinants of the variant sequences are expressed in terms of homology, the skilled worker can use routine techniques, such as homology mapping, to further identify candidate nucleotides which meet the structural aspects recited in the claims.

(C) Reply: It is unclear what is meant by "the structural determinants of the variant sequences are expressed in terms of homology". The Office fails to see where the specification provides guidance as to how any structural determinants, including domains, motifs, and amino acid residues of SEQ ID NO: 2, may or may not be altered and still retain the desired activity. Without such guidance, the identification of nucleic acid molecules having the desired characteristics requires undue experimentation.

(D) Conserved amino acid substitutions (see infra for a discussion thereof) could be used as high-stringency filters.

Additionally, as is routinely conducted in bioinformatics, variant sequences having an abrupt stop codon, no start codon, etc. can be removed from this pool.

(D) Reply: The Office fails to see where the instant response discusses "conserved amino acid substitutions".

While, variant sequences having an abrupt stop codon or no start codon may be removed, the recited genus encompasses an essentially unlimited number of nucleic acid molecules (see (A), above).

(E) As for the functional aspect recited in the claims, the skilled worker could use high throughput screening of variant sequences, for example, using FRET studies described in Applicants' own specification. Other high-throughput techniques for studying protein-protein interactions, for example, mammalian-2-hybrid or yeast-2-hybrid screens, may also be utilized. Reagents and methodologies used in such assays were known to the skilled worker before the earliest priority date.

(E) Reply: It is acknowledged that high through-put methods for detecting protein/protein interaction were known in the art. However, the instant claims are so broad as to encompass the genus of any nucleic acid molecule comprising a polynucleotide having at least 95% or 90% identity with any nucleic acid molecule comprising SEQ ID NO: 1, wherein said genus of nucleic acid molecules encodes a polypeptide that binds to the PKA regulatory subunit II. Said genus encompasses a sub-genus of nucleic acid molecules, wherein the region not homologous to SEQ ID NO: 1 encodes a polypeptide sequence that binds to PKA regulatory subunit II. The specification fails to provide any example of said sub-genus or to provide guidance as to how to make and use the encompassed nucleic acid molecules. Identification of nucleic acid molecules having the desired structural and functional characteristics requires undue experimentation.

For these reasons and those explained in the prior actions, Claims 1, 3, 4, 9, 10, 22, and 23 are rejected under 35 U.S.C. 112, first paragraph/enablement.

Written Description

The rejection of Claims 1, 3, 4, 9, and 10 under 35 U.S.C. 112, first paragraph/written description, for essentially the same reasons explained in the prior actions, is maintained. Claims 22 and 23 are herein rejected first paragraph/written description, for the same reasons.

Examiner's note: The action of November 6, 2007 rejected Claims 1, 4, 9, and 10 under 35 U.S.C. 112, first paragraph/written description. The action of July 30, 2008 maintained the rejected of Claims 1, 4, 9, and 10, and further rejected Claim 20 under 35 U.S.C. 112, first paragraph/written description. In the action of September 1, 2009, due to typographical error, the introductory paragraph of the 35 U.S.C. 112, first paragraph/written description, failed to list Claims 1, 3, 4, 9, and 10. Nonetheless, the skilled artisan would have understood this as a typographical error because (1) discussion of the rejection described why the rejection of Claims 1, 3, 4, 9, and 10 was maintained and (2) Applicants discuss Claims 1, 3, 4, 9, and 10 in the instant response (pg 8, parg 2).

In support of their request that said rejection be withdrawn, Applicants provide the following arguments. These arguments are not found to be persuasive for the reasons in each reply.

(A) The pending claims have been amended. One aspect of Applicants' invention, which is claimed herein, is directed to polynucleotide sequences comprising at least 95% homology to SEQ ID NO: 1 and which encode proteins having PKA-regulatory subunit II-binding activity.

(A) Reply: It is acknowledged that the pending claims have been amended to recite "at least 95% homology to SEQ ID NO: 1" and "PKA-regulatory subunit II-binding activity". However, as explained above for enablement, the instant claims are so broad as to encompass the

genus of any nucleic acid molecule comprising a polynucleotide having at least 95% or 90% identity with any nucleic acid molecule comprising SEQ ID NO: 1, wherein said genus of nucleic acid molecules encodes a polypeptide that binds to the PKA regulatory subunit II. Said genus encompasses a sub-genus of nucleic acid molecules, wherein the region not homologous to SEQ ID NO: 1 encodes a polypeptide sequence that binds to PKA regulatory subunit II. The specification fails to provide any example of said sub-genus or to describe said sub-genus such that the skilled artisan would recognize possession.

(B) It is submitted that present claim 1 conforms to exemplary claims 1 and 2 of Example 11B beginning on Page 39 of the Training Materials (Rev. 1, March 25, 2008) of the PTO's new Written Description Guidelines.

(B) Reply: Applicants have merely asserted that Claim 1 conforms to Example 11B without providing an analysis of how Claim 1 so conforms. It is acknowledged that Claim 1, similar to Claim 2 of Example 11B, recites a polynucleotide encoding a variant polypeptide having a biological activity.

However, regarding guidance and teachings, Claim 1 herein is not analogous to Claim 2 of Example 11B. Analysis of said Claim 2 states that the specification teaches two domains that are required for the desired biological activity. Said teachings provide a correlation between structure and function and, thus, guide the skilled artisan as to which of the encompassed polynucleotides encode proteins having the desired activity. In contrast, Applicants fail to point to or provide evidence for a correlation between structure and function and, thus, do not guide the skilled artisan as to which of the encompassed polynucleotides encode proteins having the desired activity.

In addition, Claim 1 herein does not conform to exemplary Claims 1 and 2 of Example 11B of the PTO's new Written Description Guidelines because Claim 1 herein uses "comprising" language. See (A), above.

(C) The instant claims are different from University of California v. Lilly, 964 F.2d 1128 (Fed.Cir. 1997) or University of Rochester v. Searle, 358 F.3d 1303 (Fed.Cir. 2004) where functional language was involved with insufficient structural details available for a chemical compound.

(C) Reply: The instant claims are not different from University of California v. Lilly, 964 F.2d 1128 (Fed.Cir. 1997) or University of Rochester v. Searle, 358 F.3d 1303 (Fed.Cir. 2004). The instant claims recite functional language with insufficient structural details available for the encompassed genus of polynucleotides. See (A), above.

(D) These facts here are similar to those in Capon v. Eshhar, 76 USPQ2d 1078, 1082 (Fed. Cir. 2005) and Falkner v. Inglis, 448 F.3d 1357 (Fed.Cir. 2006). In these cases, the court held that even where there are no examples within the scope of a claimed genus, a written description exists where the elements of the members of the genus are known. Here, based on the complete disclosed AKAP8 polynucleotide sequence (i.e., SEQ ID NO: 1), variant sequences are also comprehensible without explicitly listing each and every sequence. The specification provides representative examples of polynucleotide sequences which fall within this genus of polynucleotides, for example, SEQ ID NO: 1 and degenerates thereof. Furthermore, in view of the detailed level of knowledge in molecular biology and the sophisticated tools available to the skilled worker, any variant sequence which meets the claimed structural (i.e., nucleotide sequence) can be can be generated. For example, the sequences can be generated using

Lasergene Software available via DNAstar Inc. Additionally, functional features (e.g., PKA regulatory subunit II- binding ability, as taught by the present specification) of these variants can be routinely tested, for example, using assays that are described in the present specification. Explicit description is therefore not necessary.

(D) Reply: It is acknowledged that examples of reduction to practice are not required for to satisfy the written description requirement when elements of the members of the genus are known. However, the instant claims encompass any nucleic acid molecule comprising a polynucleotide having at least 95% or 90% identity with any nucleic acid molecule comprising SEQ ID NO: 1, wherein said genus of nucleic acid molecules encodes a polypeptide that binds to the PKA regulatory subunit II. Said genus encompasses a sub-genus of nucleic acid molecules, wherein the region not homologous to SEQ ID NO: 1 encodes a polypeptide sequence that binds to PKA regulatory subunit II. The specification fails to describe any such elements of said sub-genus such that the skilled artisan would recognize possession.

Claims 1-5, 9, 10, and 22 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. Claims 1 and 22 introduce the limitation of "95% homology to a nucleic acid sequence comprising the polynucleotide of SEQ ID NO: 1". The specification fails to describe said limitation and, thus, Claims 1 and 22, and dependent Claims 2, 4, 9, and 10, are rejected under 35 U.S.C. 112, first paragraph, for introducing New Matter.

Allowable Subject Matter

Claims 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants'

remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652